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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,108	10/12/2005	Nobuo Mochizuki	20241/0203481-US0	8647
7278	7590	03/01/2010		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER HAYLIN, ROBERT H	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			03/01/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,108

**Applicant(s)**

MOCHIZUKI ET AL.

**Examiner**

ROBERT HAVLIN

**Art Unit**

1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 5 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 13-15, 17, 18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Status of the claims:** Claims 1, 3, 5, and 13-20 are currently pending.

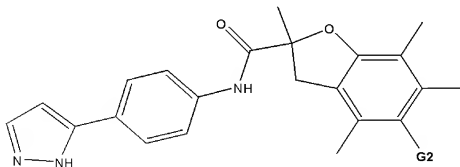
**Priority:** This application is a 371 of PCT/JP04/05237 04/13/2004 and claims foreign priority to JAPAN 2003-109667 (04/14/2003) and JAPAN 2004-023032 (01/30/2004).

**RCE:** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/19/2010 has been entered.

### *Election/Restrictions*

1. Applicant previously elected Group I (claims 1-3, 5, 6, and 13) in the reply filed on 9/19/07.

Applicant also elected the species of Compound 37 reading on claims 1-3, 5, 13, and 14 with the following structure (G2=NH2):



As detailed below, the generic claim was found unpatentable and in accordance with the election of species practice described in the requirement for restriction, subject

matter not reading on the elected species is hereby withdrawn. Accordingly, claims 16 and 19 are hereby withdrawn.

***Declaration***

The declaration of Seiichi Uchida under 37 CFR 1.132 filed 1/19/2010 is insufficient to overcome the rejection of claims 1, 3, 5, 13-15, 17, 18, and 20 based upon 35 USC 103 as set forth in the last Office action for the following reasons.

Applicant has presented data in the declaration but has not demonstrated that the results are statistically significant. Specifically, the data used to compare the two compounds do not indicate the confidence intervals that would allow the examiner to properly evaluate whether the results were, in fact, unexpected. As recommended previously, the examiner again requests applicant to provide the relevant statistical confidence interval pertaining to the values in the declaration. This is required to meet applicants burden as required by MPEP § 716.02(b).

**RESPONSE TO APPLICANT ARGUMENTS**

***Claim Rejections - 35 USC § 112***

2. Claims 1, 3, 5, and 14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has deleted the indefinite "substituted" language, therefore this rejection is **withdrawn**.

***Claim Rejections - 35 USC § 103***

3. Claims 1-3, 5, 13-15, 17, 18 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,342,516 ('516) in view of Patani et al. (Chem. Rev., 1996, Vol. 96, No. 8, P. 3147-3176).

Applicant argues that the 132 declaration establishes the nonobviousness of the claims. Because the 132 declaration was not found persuasive as to the nonobviousness of the claims, this rejection is **maintained**.

***Conclusion***

No generic claim was held allowable, the claims are restricted to the elected species only and the remaining subject matter held withdrawn. The claims are not in condition for allowance.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626

/Kamal A Saeed/  
Primary Examiner, Art Unit 1626